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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,453	08/31/2005	Cesare Puricelli	206,871	8650

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EXAMINER

TYSON, MELANIE RUANO

ART UNIT	PAPER NUMBER
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3731

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07/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/524,453

Applicant(s)

PURICELLI ET AL.

Examiner

Melanie Tyson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6 and 8-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-6, and 8-14 is/are rejected.
- 7) ☒ Claim(s) 4 and 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

This action is in response to Applicant's amendment received on 16 April 2007.

Corrections made have been accepted.

Claim Objections

1. Claims 4 and 5 are objected to because of the following informalities: claims 4 and 5 depend from claim 3, which has been cancelled. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Burkhart (Patent No. 5,368,596). Burkhart discloses an instrument (Figure 1) capable of piercing the sternum since it pierces bone (column 4, lines 65-68). The instrument comprises a first jaw (36a) having a punching tip (37a) and a second jaw (36b) having a protuberance (tip 37b) facing the first jaw (36a), wherein a portion of the surface forms an acute angle (surface is slanted) with the axis of the punching tip (37a). Burkhart further discloses handles (18a and 18b) for moving the tip (37a) closer to the second jaw (36b).

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Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1, 2, 4, 6, 8, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilmer (Patent No. 4,723,540). Gilmer discloses a titanium bone staple (Figure 2; column 2, lines 65-68), two internal threaded parts (14, 16; column 3, lines 1-5), two teeth (20, 30) each having a leg (24, 34) and a threaded end (22, 32). Gilmer further discloses an apparatus (Figure 5) equipped with a clutch (jaws 46, 47, and 48) to rotate the cylindrical body of the staple (column 4, lines 27-47). The bone staple (10) and the apparatus used to rotate the staple are reasonably understood to comprise a "surgical kit" since Gilmer discloses they are usable together in order to repair bone injuries and disorders.

With further respect to claims 1, 4, and 12, forming the legs having an acute angle with the threaded end, or with an angle less than 90 degrees, or between 70 and

85 degrees, would have been obvious to one of ordinary skill in the art at the time the invention was made, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. Furthermore, it is well known in the art to form the legs of surgical staples having acute angles (for example, see Figure 14 of Allen, 2002/0173793 A1).

With further respect to claim 8, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the legs having a length between 10 and 20 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

7. Claims 1 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Attenborough (3,807,394). Attenborough discloses a device (see entire document) including a central body (1) having two threaded parts (for example, see Figure 2), and two teeth (5) each having a threaded end (6) to engage the threaded parts of the central body (1).

With further respect to claim 1, forming the legs having an acute angle with the threaded end, or with an angle less than 90 degrees, would have been obvious to one of ordinary skill in the art at the time the invention was made, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. Furthermore, it is well known in the art to form the legs of surgical staples having acute angles (for example, see Figure 14 of Allen, 2002/0173793 A1).

With further respect to claim 5, constructing the staple with rounded tips is simply a change in shape of the tips, which involves routine skill in the art. Since it is well known in the art that staples may be made with rounded tips, it would have been obvious to one of ordinary skill in the art at the time the invention was made as a matter of design choice to construct the staple of Attenborough with rounded tips (for example, see Figure 30 of Lemer, 6,368,342 B1).

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burkhart. Burkhart discloses a device as described above, however, does not disclose the angle between a portion of the second jaw and the axis of the punching tip is between 70 and 85 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the angle between a portion of the second jaw and the axis of the punching tip between 70 and 85 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

9. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilmer in view of Burkhart. Gilmer discloses a "kit" as described above, however, does not disclose punch cutter forceps. Burkhart discloses an instrument (Figure 1) capable of making holes in a sternum since the instrument pierces bone (column 4, lines 65-68). The instrument comprises a first jaw (36a) having a punching tip (37a) and a second jaw (36b) having a protuberance (tip 37b) facing the first jaw (36a), wherein a portion of the surface forms an acute angle (surface is slanted) with the axis of the punching tip (37a). Burkhart further discloses handles (18a and 18b) for moving the tip

(37a) closer to the second jaw (36b). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the instrument taught by Burkhart in the surgical kit of Gilmer in order to create a channel for the staple (column 1, lines 9-13).

Response to Arguments

10. Applicant's arguments filed 16 April 2007 with respect to claims 1, 2, 4-6, and 8 have been considered but are moot in view of the new ground(s) of rejection.

11. Applicant's arguments filed 16 April 2007 with respect to claims 9-14 have been fully considered but they are not persuasive. Applicant argues primarily that the prior art references do not disclose each and every element claimed. Examiner respectfully disagrees.

With respect to claims 9-11, Applicant argues that the first jaw, of Burkhart, approaches the second jaw according to a circular trajectory rather than a rectilinear trajectory as claimed. However, the tip of Burkhart moves closer to the second jaw according to a rectilinear trajectory in that the tip moves in a straight path towards the second jaw when the handles are operated. The tip of Burkhart does not move in a circular path towards the second jaw as Applicant suggests.

With respect to claims 12-14, Applicant argues that Gilmer does not disclose a clutch, in that Gilmer does not disclose "a device capable of automatically interrupting rotation when a predetermined torque, corresponding to a predetermined tension, is reached." However, this limitation is not claimed. Applicant simply claims "a clutch able to rotate the cylindrical body of a staple...up to a present tension of the staple." Claim

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12 has been given the broadest reasonable interpretation, in that a clutch includes claws, for example, in the act of grasping or seizing firmly (for example, see Merriam-Webster Online Dictionary), which Gilmer discloses (see rejection above).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 9-5:30, Fridays 8-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson
July 1, 2007



(JACKIE) TAN-UYEN HO
SUPERVISORY PATENT EXAMINER
7/3/07th